

REMARKS

Interview

The undersigned greatly appreciates the telephone interview on May 11, 2006, with the examiner Daniel Gamett and supervisor David Romeo. As discussed, there are several related applications pending, and it is important that the prosecution of these cases be coordinated so that the claim language is consistent and the examiner is fully aware of the arguments made in the related cases. These include U.S.S.N. 10/792,302 "Isolation of Spore-Like Cells From Tissues Exposed to Extreme Conditions" by Charles A. Vacanti and Martin P. Vacanti which will issue on June 13, 2006, and has been assigned U.S. Patent No. 7,060,492 (our ref: VAC104); Serial No.: 10/462,034 filed June 13, 2003 "Spore-like cells and uses thereof" (our ref: VAC 103); Serial No.: 10/379,394 filed March 3, 2003 "Compositions and Methods for Generating Skin" (our ref: VAC 105); Serial No.: 10/688,305 filed: October 17, 2003 "Biological Scaffolding Material" (our ref: VAC 106); U.S. Patent No. 5,944,754 "Tissue Resurfacing with Hydrogel-Cell Compositions" by Charles A. Vacanti (our ref: VAC 100); U.S. Patent No. 6,027,744 "Guided Development and Support of Hydrogel-Cell Compositions" by Charles A. Vacanti and Joseph P. Vacanti (VAC 101).

Drawings

Please confirm that the amendments to the specification, and the previously submitted remarks, have overcome the previous objections to the drawings.

Title

The title was amended to refer to a "Population of Neuroendocrine Stem Cells in a Hydrogel Support". In view of the discussion regarding the use of the phrase "undifferentiated" rather than "stem" cell, it is suggested this title should be further amended as shown.

"Population of Undifferentiated Neural, Endocrine or Neuroendocrine Stem Cells in a Hydrogel Support".

Amendments to the Claims

To moot the examiner's concern regarding "neuroendocrine tissue", the claim has been amended to reference neural (see, for example, page 6, lines 6-12); endocrine or neuroendocrine (see, for example, page 5, lines 26-31; page 26).

The reference to "stem" cell has also been deleted. Support for differentiation is found throughout the specification, and explicitly in the examples, see, in particular, examples 5-8, page 49 table showing differentiation into a wide range of cells, from cells from numerous types of tissues (pages 50-52), which also provides support for new claim 62.

Claim 43 has also been amended to require a support structure, as defined in more detail by the dependent claims, and demonstrated by the examples.

Rejections under 35 U.S.C. 112

Claims 43, 44 and 54-58 were rejected under 35 U.S.C. 112 as lacking enablement. This rejection is respectfully traversed.

As discussed by phone and above, the claims have been amended to recite neural, endocrine and neuroendocrine to more clearly define the source of the claimed cell populations. As demonstrated by the examples and at page 6, lines 18-33; page 26, lines 15-25; page 27 lines 9-22; see especially page 44, lines 15-29, and pages 49-52, applicants have demonstrated

isolation of the claimed cell population from a number of different cells types, as well as demonstrated that these cells differentiate into numerous tissue types. The specification teaches not only how to obtain the cells but how to keep the cells in culture in an undifferentiated form.

It is believed the claims are clearly enabled in view of the amendments and foregoing discussion.

Rejection under 35 U.S.C. 102

Claims 43 and 44 were rejected under 35 U.S.C. 102(b) as disclosed by Cornelius, et al., *Horm. Metab. Res.* 29(6):271-277 (1997). This rejection is respectfully traversed if applied to the amended claims.

As discussed during the telephone interview, the claims have been amended to require a support structure for implantation and Cornelius does not disclose such a structure. Therefore the claims are novel over the cited art.

In summary, the claims are drawn to definite, enabled, and novel subject matter. The specification demonstrates that the claimed subject matter was fully reduced to practice and described generally and as a working example in the specification as originally filed, in compliance with all requirements under 35 U.S.C. 112.

Allowance of claims 43, 44 and 54-62 is earnestly solicited.

Respectfully submitted,

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